CLAIMS.

What is claimed is:

1. An implantable biopsy cavity marking device comprising at least one body comprising a resilient biocompatible material, wherein the marking device is radiopaque and echogenic.

2. The device of claim 1 wherein the at least one body comprises a non-bioabsorbable material.

3. The device of claim 1 wherein the marking device further comprises an X-ray detectable object of specific predetermined non-biological configuration embedded in the body of the marking device.

4. The device of claim 2 wherein the X-ray detectable object comprises a material selected from the group consisting of platinum, iridium, nickel, tungsten, tantalum, gold, silver, rhodium, titanium, alloys thereof, and stainless steel.

5. The device of claim 4 wherein the biocompatible material comprises a polymer.

6. The device of claim 5 wherein the polymer is one or more polymers selected form the group consisting of polyacrylates, ethylene-vinyl acetate polymers, non-erodible polyurethanes, polystyrenes, polyvinyl chloride, polyvinyl fluoride, poly(vinyl imidazole), chlorosulphonated polyolifins, polyethylene oxide, polyvinyl alcohol, teflon, calcium carbonate, carrageenan and nylon, and derivatives thereof.

7. The device of claim 5 wherein the polymer is selected form the group consisting of a polyvinyl alcohol gel, foam or sponge, hydrogel, and esters and acylation derivatives thereof.

8. The device of claim 7 wherein the polymer is a hydrogel selected from the group consisting of a crosslinked polyethylene oxide, polypropylene oxide, polyvinyl alcohol, polyvinyl acetate, polyvinyl pyrrolidone, polyhydroxyalkyl acrylate, polystyrene sulfonate and copolymers or combinations thereof. .

9. The device of claim 4 wherein the biocompatible material comprises a polymer having a radiopaque additive.

10. The device of claim 5 wherein the radiopaque additive is selected from the group consisting of barium-containing compounds, bismuth-containing compounds, powdered tantalum, powdered tungsten, barium carbonate, bismuth oxide, and barium sulfate.

11. The device of claim 7 wherein the polymer material is a two-part hydrogel material that is blended at the time of injection to a biopsy site.

12. The device of claim 7 additionally comprising an active agent for delivery at a biopsy site.

13. The device according to claim 12 wherein the active agent comprises at least one agent selected from the group consisting of a chemotherapeutic agent, a radiation agent and a gene therapy agent.

14. The device of claim 6 additionally comprising at least one agent selected from the group consisting of a pain killing substance, a hemostatic substance, an antibiotic, and a radioactive material.

15. The device of claim 6 wherein the polymer is of a different hardness in the post-delivery state as in the pre-delivery state.

16. The device according to claim 6 wherein the polymer has a hardness of about 0.5 times to about 1.5 times as hard as breast tissue in the post-delivery state.

17. The device according to claim 6 wherein the polymer swells about 50 to 1500 percent from the pre-delivery state to the post-delivery state when placed in contact with an aqueous liquid.

18. The device according to claim 6 wherein the polymer has a first shape in the pre-delivery state and a second, predetermined shape in the post-delivery state.

19. The device according to claim 6 wherein the polymer has one consistency in the pre-delivery state and a different consistency in the post-delivery state.

20. The device of claim 3 wherein the X-ray detectable object comprises a wire.

21. The device of claim 25 wherein the object has a distinguishing shape.

22. The device of claim 25 wherein the object is fixedly attached to the at least one body.

23. The device of claim 25 wherein the object is radioactive.

24. The device of claim 4 wherein the at least one body is radioactive.

25. The device of claim 6 wherein the biocompatible material further comprises a bio-resorbable polymeric material.

26. The device of claim 6 wherein the bio-resorbable polymeric material is selected from the group consisting of poly(esters), poly(hydroxy acids), poly(lactones), poly(amides), poly(ester-amides), poly(amino acids), poly(anhydrides), poly(ortho-esters), poly(carbonates), poly(phosphazines), poly(thioesters), poly(urethanes),

poly(ester urethanes), polysaccharides, polylactic acids, polyglycolic acids, polycaproic acids, polybutyric acids, polyvaleric acids, and copolymers, polymer alloys, polymer mixtures, and combinations thereof.

27. The device of claim 6 wherein the bio-resorbable polymeric material has a bulk density of between about 0.8 g/ml and about 1.5 g/ml.

28. The device of claim 6 further comprising a binding agent.

29. The device of claim 33 wherein the binding agent is selected from the group consisting of gelatin, polyethylene glycol, polyvinyl alcohol, glycerin, acrylic hydrogels, organic hydrogels, and combinations thereof.

30. The device of claim 33 wherein the binding agent comprises gelatin selected from the group consisting of bovine collagen, porcine collagen, ovine collagen, equine collagen, synthetic collagen, agar, synthetic gelatin, and combinations thereof.

31. An implantable biopsy cavity marking device comprising at least one body comprising a resilient biocompatible polymeric material encapsulated within a biodegradable shell wherein the shell degrades upon contact with a liquid and wherein the marking device is radiopaque and echogenic.

32. The device of claim 31 wherein the polymeric material comprises a non-bioabsorbable material.

33. The device of claim 32 wherein the polymeric material within the shell is compressed foam or is a material selected from the group consisting of materials reactive with body fluids, liquids, binding agents, active agents or combinations thereof.

34. The device of claim 33 wherein the marking device further comprises an X-ray detectable object of specific predetermined non-biological configuration embedded in the body of the marking device.

35. The device of claim 32 wherein the marking device further comprises a radiopaque additive selected from the group consisting of barium-containing compounds, bismuth-containing compounds, powdered tantalum, powdered tungsten, barium carbonate, bismuth oxide, and barium sulfate.

36. The device of claim 32 wherein the polymeric material is one or more polymers selected form the group consisting of polyacrylates, ethylene-vinyl acetate polymers, non-erodible polyurethanes, polystyrenes, polyvinyl chloride, polyvinyl fluoride, poly(vinyl imidazole), chlorosulphonated polyolifins, polyethylene oxide, polyvinyl alcohol, teflon, calcium carbonate, carrageenan and nylon, and derivatives thereof.

37. The device of claim 32 wherein the polymeric material is selected form the group consisting of a polyvinyl alcohol gel, foam or sponge, hydrogel, and esters and acylation derivatives thereof.

38. The device of claim 32 wherein the polymer is a hydrogel selected from the group consisting of a crosslinked polyethylene oxide, polypropylene oxide, polyvinyl alcohol, polyvinyl acetate, polyvinyl pyrrolidone, polyhydroxyalkyl acrylate, polystyrene sulfonate and copolymers or combinations thereof. .

39. The device of claim 32 wherein the shell is a layer of bioabsorbable material.

40. The device of claim 33 wherein the bio-resorbable polymeric material is selected from the group consisting of collagen, cross-linked collagen, regenerated cellulose, synthetic polymers, synthetic proteins, and combinations thereof.

41. The device of claim 33 wherein the bio-resorbable polymeric material is selected from the group consisting of poly(esters), poly(hydroxy acids), poly(lactones), poly(amides), poly(ester-amides), poly(amino acids), poly(anhydrides), poly(ortho-esters), poly(carbonates), poly(phosphazines), poly(thioesters), poly(urethanes), poly(ester urethanes), polysaccharides, polylactic acids, polyglycolic acids, polycaproic acids, polybutyric acids, polyvaleric acids, and copolymers, polymer alloys, polymer mixtures, and combinations thereof.

42. The device of claim 33 wherein the polymer material is a two-part hydrogel material.

43. The device of claim 33 additionally comprising an active agent for delivery at a biopsy site.

44. The device according to claim 44 wherein the active agent comprises at least one agent selected from the group consisting of a chemotherapeutic agent, a radiation agent and a gene therapy agent.

45. The device of claim 33 wherein the polymeric material is of a different hardness in the post-delivery state as in the pre-delivery state.

46. The device according to claim 33 wherein the polymeric material has a hardness of about 0.5 times to about 1.5 times as hard as breast tissue in the post-delivery state.

47. The device according to claim 33 wherein the polymeric material swells about 50 to 1500 percent from the pre-delivery state to the post-delivery state when placed in contact with a liquid.

48. The device according to claim 33 wherein the polymer has a first shape in the pre-delivery state and a second shape in the post-delivery state.

49. The device according to claim 33 wherein the polymer has one consistency in the pre-delivery state and a different consistency in the post-delivery state.

50. The device of claim 35 wherein the X-ray detectable object comprises a wire.

51. The device of claim 51 wherein the object has a distinguishing shape.

52. The device of claim 51 wherein the object is fixedly attached to the at least one body.

53. The device of claim 51 wherein the object is radioactive.

54. The device of claim 33 wherein the at least one body is radioactive.

55. The device of claim 33 wherein the biocompatible material further comprises a bio-resorbable polymeric material.

56. The device of claim 33 wherein the bio-resorbable polymeric material is selected from the group consisting of poly(esters), poly(hydroxy acids), poly(lactones), poly(amides), poly(ester-amides), poly(amino acids), poly(anhydrides), poly(ortho-esters), poly(carbonates), poly(phosphazines), poly(thioesters), poly(urethanes), poly(ester urethanes), polysaccharides, polylactic acids, polyglycolic acids, polycaproic acids, polybutyric acids, polyvaleric acids, and copolymers, polymer alloys, polymer mixtures, and combinations thereof.

57. The device of claim 56 wherein the bio-resorbable polymeric material has a bulk density of between about 0.8 g/ml and about 1.5 g/ml.

58. The device of claim 33 further comprising a binding agent.

59. The device of claim 33 wherein the binding agent is selected from the group consisting of gelatin, polyethylene glycol, polyvinyl alcohol, glycerin, acrylic hydrogels, organic hydrogels, and combinations thereof.

60. The device of claim 33 wherein the binding agent comprises gelatin selected from the group consisting of bovine collagen, porcine collagen, ovine collagen, equine collagen, synthetic collagen, agar, synthetic gelatin, and combinations thereof.

61. A method of marking a biopsy site within a subject's body, comprising depositing an implantable biopsy cavity marking device comprising at least one body comprising a resilient biocompatible material, wherein the marking device is radiopaque and echogenic.

62. The method of claim 61 wherein the at least one body comprises a non-bioabsorbable material.

63. The method of claim 62 wherein the marking device further comprises an X-ray detectable object of specific predetermined non-biological configuration embedded in the body of the marking device.

64. The method of claim 63 wherein the marker comprises a material selected from the group consisting of platinum, iridium, nickel, tungsten, tantalum, gold, silver, rhodium, titanium, alloys thereof, and stainless steel.

65. The method of claim 63 wherein the biocompatible material comprises a polymer.

66. The method of claim 65 wherein the polymer is one or more polymers selected form the group consisting of polyacrylates, ethylene-vinyl acetate polymers, non-erodible polyurethanes, polystyrenes, polyvinyl chloride, polyvinyl fluoride, poly(vinyl imidazole), chlorosulphonated polyolifins, polyethylene oxide, polyvinyl alcohol, teflon, calcium carbonate, carrageenan and nylon, and derivatives thereof.

67. The method of claim 65 wherein the polymer is a polyvinyl alcohol gel, foam, sponge, swellable polymer, hydrogels and acylation derivatives thereof, including esters.

68. The method of claim 67 wherein the polymer is a hydrogel selected from the group consisting of a crosslinked polyethylene oxide, polypropylene oxide, polyvinyl alcohol, polyvinyl acetate, polyvinyl pyrrolidone, polyhydroxyalkyl acrylate, polystyrene sulfonate and copolymers or combinations thereof. .

69. The method of claim 68, wherein the material is effective to form a gel upon introduction within the body of an animal.

70. The method of claim 68, wherein the material forms a gel upon introduction within the body of an animal after contact with a biocompatible liquid.

71. The method of claim 70, wherein the biocompatible liquid comprises a hemostatic agent selected from the group consisting of tissue fluid, water, binding agents, active agents, liquid polymers, hemostatic agents,

72. The method of claim 70, wherein the biocompatible liquid comprises a pharmaceutical agent selected from the group consisting of penicillins, cephalosporins, vancomycins, aminoglycosides, quinolones, polymyxins, erythromycins, tetracyclines, streptomycins, sulfa drugs, chloramphenicols, clindamycins, lincomycins, sulfonamides, paclitaxel, docetaxel, acetyl sulfisoxazole, alkylating agents, antimetabolites, plant alkaloids, mechlorethamine, chlorambucil, cyclophosphamide, melphalan, ifosfamide, methotrexate, 6-mercaptopurine, 5-fluorouracil, cytarabine, vinblastine, vincristine, etoposide, doxorubicin, daunomycin, bleomycin, mitomycin, carmustine, lomustine, cisplatin, interferon, asparaginase, tamoxifen, flutamide, amantadines, rimantadines, ribavirins, idoxuridines, vidarabines, trifluridines, acyclovirs, ganciclovirs, zidovudines, foscarnets, interferons, prochlorperzine edisylate, ferrous sulfate, aminocaproic acid, mecamylamine hydrochloride, procainamide hydrochloride, isoproterenol sulfate,

phenmetrazine hydrochloride, bethanechol chloride, methacholine chloride, isopropamide iodide, tridihexethyl chloride, phenformin hydrochloride, methylphenidate hydrochloride, theophylline cholinate, cephalexin hydrochloride, diphenidol, meclizine hydrochloride, prochlorperazine maleate, phenoxybenzamine, thiethylperzine maleate, anisindone, diphenadione erythrityl tetranitrate, isoflurophate, acetazolamide, methazolamide, bendroflumethiazide, chloropromaide, tolazamide, chlormadinone acetate, phenaglycodol, allopurinol, aluminum aspirin, hydrocortisone, hydrocorticosterone acetate, cortisone acetate, dexamethasone and its derivatives such as betamethasone, triamcinolone, methyltestosterone, 17-S-estradiol, ethinyl estradiol, ethinyl estradiol 3-methyl ether, prednisolone, 17-hydroxyprogesterone acetate compounds, 19-nor-progesterone, norgestrel, norethindrone, norethisterone, norethiederone, progesterone, norgesterone, norethynodrel, aspirin, indomethacin, naproxen, fenoprofen, sulindac, indoprofen, nitroglycerin, isosorbide dinitrate, propranolol, timolol, atenolol, alprenolol, cimetidine, clonidine, imipramine, dihydroxyphenylalanine, theophylline, calcium gluconate, ketoprofen, ibuprofen, cephalexin, haloperidol, zomepirac, ferrous lactate, vincamine, diazepam, phenoxybenzamine, milrinone, capropril, mandol, quanbenz, hydrochlorothiazide, ranitidine, flurbiprofen, fenufen, fluprofen, tolmetin, alclofenac, mefenamic, flufenamic, difuinal, nizatidine, sucralfate, etintidine, tetratolol, minoxidil, chlordiazepoxide, diazepam, amitriptyline, imipramine, prostaglandins, coagulation factors, analogs of these compounds, derivatives of these compounds, and pharmaceutically acceptable salts of these compounds, analogs and derivatives.

73. The method of claim 70, wherein the biocompatible liquid comprises a hemostatic agent selected from the group consisting of adrenochrome, algin, alginic acid, aminocaproic acid, batroxobin, carbazochrome salicylate, cephalins, cotarmine,

ellagic acid, epinephrine, ethamsylate, factor VIII, factor IX, factor XIII, fibrin, fibrinogen, naphthoquinone, oxamarin, oxidized cellulose, styptic collodion, sulamrin, thrombin, thromboplastin (factor III), tolonium chloride, tranexamic acid, and vasopression.

74. The method of claim 68, wherein the quantity of ultrasound-detectable material comprises a slurry of ultrasound-detectable material in a biocompatible liquid.

75. The method of claim 74, wherein the slurry is formed within a delivery tube.

76. The method of claim 74, wherein the slurry is formed within a syringe.

77. The method according to claim 74 wherein the device is positioned by a positioning step carried out by at least one of: injecting a flowable polymer through a hollow member; pushing a nonflowable polymer through a hollow member; and guiding a solid polymer to the target site.

78. The method according to claim 77 wherein the flowable polymer injecting step is carried out using a biopsy needle.

79. The method according to claim 77 further comprising the step of changing the polymer from a pre-delivery state prior to the positioning step to a post-delivery state after the positioning step.

80. The method according to claim 79 wherein the changing step is carried out by at least one of the following: hydration, changing temperature, electrical stimulation, magnetic stimulation, chemical reaction with a first additional material, physical interaction with a second additional material, ionization, absorption and adsorption.

81. The method according to claim 77 further comprising the step of placing a marker element at a generally central location within the polymer at the target site.

82. The method according to claim 81 wherein the biopsy site relocating step comprises the step of remotely visualizing the marker element.

83. The method according to claim 74 wherein the method further comprises: testing the tissue sample and, if the testing indicates a need to do so, medically treating the biopsy site.

84. The method according to claim 75 wherein the medically treating step comprises activating an agent carried by the polymer.

85. The method according to claim 76 wherein the activating step is carried out by at least one of: injecting a radiation-emitting element at the vicinity of the target site; externally irradiating the target site; and providing a triggering substance to the agent.

86. The method according to claim 75 wherein the medically treating step comprises delivering a therapeutic agent to the target site.

87. The method according to claim 68 wherein the delivering step is carried out using at least one of: a chemotherapy agent; a radiation-emitting element; thermal energy; ionization energy; gene therapy; vector therapy; electrical therapy; vibrational therapy; and anti-angiogenesis.

88. The method according to claim 79 further comprising the step of relocating the biopsy by finding the polymer.

89. The method according to claim 83 wherein the medical treating step comprises removal of tissue.

90. The method according to claim 65 wherein the marking device comprises at least one body comprising a resilient biocompatible polymeric material encapsulated within a biodegradable shell wherein the shell.

91. The method of claim 90 wherein the shell is a layer of bioabsorbable material that degrades upon contact with a liquid.

92. The method of claim 91 wherein the bio-resorbable polymeric material is selected from the group consisting of collagen, cross-linked collagen, regenerated cellulose, synthetic polymers, synthetic proteins, and combinations thereof.

93. The method of claim 92 wherein the bio-resorbable polymeric material is selected from the group consisting of poly(esters), poly(hydroxy acids), poly(lactones), poly(amides), poly(ester-amides), poly(amino acids), poly(anhydrides), poly(ortho-esters), poly(carbonates), poly(phosphazines), poly(thioesters), poly(urethanes), poly(ester urethanes), polysaccharides, polylactic acids, polyglycolic acids, polycaproic acids, polybutyric acids, polyvaleric acids, and copolymers, polymer alloys, polymer mixtures, and combinations thereof.

94. The method of claim 92 wherein the marking device further comprises a binding agent.

95. The method of claim 92 wherein the binding agent is selected from the group consisting of gelatin, polyethylene glycol, polyvinyl alcohol, glycerin, acrylic hydrogels, organic hydrogels, and combinations thereof.

96. The method of claim 92 wherein the binding agent comprises gelatin selected from the group consisting of bovine collagen, porcine collagen, ovine collagen, equine collagen, synthetic collagen, agar, synthetic gelatin, and combinations thereof.